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Tris Pharma, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRIS PHARMA, INC.,	)	
Plaintiff,	)	Civil Action No. _____
v.	)	
ACTAVIS LABORATORIES FL, INC., ANDRX CORPORTATION, ACTAVIS, INC., and ACTAVIS PHARMA, INC.	)	
Defendants.	)	

COMPLAINT

1. Tris Pharma, Inc. ("Tris" or "Plaintiff"), for its Complaint against Actavis Laboratories FL, Inc. ("Actavis FL"), Andrx Corporation ("Andrx"), Actavis, Inc., and Actavis Pharma, Inc. ("Actavis Pharma") (collectively "Actavis" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

2. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 8,956,649 ("the '649 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 206049 seeking FDA approval to manufacture and commercially market their proposed product called "Methylphenidate HCl Extended Release Oral Suspension, CII" (hereinafter referred to as "Actavis's ANDA Product") containing the active ingredient methylphenidate HCl.

4. In a letter dated March 31, 2015, entitled "Notification of Certification for U.S. Patent Nos. 8,956,649 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "March 31 Notice Letter"), Actavis FL notified Tris that it intends to manufacture and commercially market Actavis's ANDA Product (a generic version of Quillivant XR®) before expiration of the '649 patent.

5. Plaintiff has filed a substantively identical action against the Defendants in the United States District Court for the District of Delaware. This action is being filed in the event that one or more of the Defendants challenge personal jurisdiction over them or venue in the Delaware court. If the Defendants do not challenge personal jurisdiction over them or venue in the Delaware court, plaintiff plans to dismiss this New Jersey action without prejudice.

THE PARTIES

6. Plaintiff Tris is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

7. Tris is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the U.S.

8. On information and belief, defendant Actavis FL is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis FL is a wholly-owned subsidiary of Andrx.

9. On information and belief, Actavis FL is in the business of manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

10. On information and belief, defendant Andrx is a corporation organized under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Andrx is a wholly-owned subsidiary of Actavis, Inc.

11. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. On information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

12. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

13. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and

belief, Actavis, Inc. holds a current and valid "Wholesale Drug & Medical Device" registration in New Jersey (Registration No. 5003854).

14. On information and belief, Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, and venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

16. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic.

17. On information and belief, Defendants share common officers and directors and are agents of each other, or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in the State of New Jersey.

18. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in *Vivus Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:14-cv-03786-FSH-MAH, D.I. 16 (D.N.J. Sept. 2, 2014);

Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al., No. 13-04740-RMB, D.I. 19, 20 (D.N.J. Sept. 25, 2013); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, No. 3:13-cv-01669-JAP-TJB, D.I. 9 (D.N.J. June 3, 2013).

19. On information and belief, Actavis FL, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

20. On information and belief, this Court has personal jurisdiction over Actavis FL by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

21. On information and belief, this Court has personal jurisdiction over Actavis Pharma by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

22. On information and belief, this Court has personal jurisdiction over Andrx by virtue of, *inter alia*: (1) its course of conduct that is designed to cause the sale of its products in New Jersey; and (2) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

23. On information and belief, this Court has personal jurisdiction over Actavis, Inc. by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; (3) its wholesale drug and medical device license in New Jersey; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

FIRST CLAIM FOR RELIEF: '649 PATENT

24. Tris realleges paragraphs 1-23 above as if set forth specifically here.

25. The '649 patent (copy attached as Exhibit A), entitled "Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product," was issued on February 17, 2015 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The '649 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension.

26. Plaintiff Tris has been and still is the owner of the '649 patent. The '649 patent will expire on February 15, 2031.

27. In the March 31 Notice Letter, Actavis FL notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '649 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '649 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

28. On information and belief, at the time the March 31 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 27 above.

29. Defendants acknowledged and represented that the March 31 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 27, above.

30. "[T]he established name of the drug product that is the subject of Actavis's ANDA is Methylphenidate HCl for Extended-release Oral Suspension, CII" and "the dosage forms of [Actavis's] proposed drug product is an extended-release oral suspension." Actavis failed to address indirect infringement relating to any limitations for claims 1-2, 4-5, 10, 13-27, 33, and 35-40 of the '649 patent thus acknowledging that Actavis's ANDA Product infringes these claims.

31. Actavis infringed one or more of the '649 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '649 patent.

32. Unless enjoined by this Court, Actavis will directly infringe the '649 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

33. Unless enjoined by this Court, Actavis will induce the infringement of the '649 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors,

and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '649 patent and in violation of 35 U.S.C. § 271(b).

34. Unless enjoined by this Court, Actavis will induce the infringement of the '649 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '649 patent and in violation of 35 U.S.C. § 271(b).

35. Unless enjoined by this Court, Actavis will contribute to the infringement of the '649 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Tris's rights under the '649 patent in violation of 35 U.S.C. § 271(c).

36. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '649 patent is not enjoined.

37. Tris does not have an adequate remedy at law for Actavis's infringement of the '649 patent.

38. In the March 31 Notice Letter, Actavis has presented no reasonable or good faith position that the '649 patent claims are invalid.

39. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment be entered that Actavis has infringed the '649 patent by submitting ANDA 206049 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of Actavis's ANDA 206049 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Methylphenidate HCl Extended Release Oral Suspension, CII" must be later than February 15, 2031, the expiration date of the patent in suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Product will directly infringe, induce and/or contribute to infringement of the '649 patent;

(d) Preliminary and permanent injunctions be granted enjoining Actavis and its officers, agents, attorneys, and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Actavis's ANDA Product until after the expiration of the '649 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(e) A permanent injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Actavis, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the '649 patent, or from actively inducing or contributing to the infringement of the '649 patent, until after the expiration of, respectively, the '649 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Product prior to the expiration of the '649 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the '649 patent remains valid, remains enforceable and has been infringed by Actavis;

(h) A judgment be entered that Actavis's defenses and claims for relief with respect to the '649 patent are limited to those presented in the March 31 Notice Letter;

(i) A judgment be entered that Actavis's conduct is exceptional;

(j) An award of attorneys' fees be granted pursuant to 35 U.S.C. § 285;

(k) An award of costs and expenses be granted in this action; and

(l) Such other relief as this Court may deem proper.

Dated: May 15, 2015

s/ Joshua S. Bratspies
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Attorneys for Plaintiff Tris Pharma, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

Tris Pharma, Inc. v. Actavis Laboratories FL, Inc., et al., filed in the U.S. District Court for the District of Delaware on May 15, 2015. This New Jersey action is substantively identical to the Delaware action. This action is being filed in the event that one or more of the defendants challenge personal jurisdiction over them or venue in the Delaware court. If the defendants do not challenge personal jurisdiction over them or venue in the Delaware court, plaintiff plans to dismiss this New Jersey action without prejudice.

Tris Pharma, Inc. v. Actavis Laboratories FL, Inc., et al., No. 1:14-cv-01309, filed in the U.S. District Court for the District of Delaware on October 15, 2014. The generic product at issue in this litigation is the same as in the Delaware action.

Dated: May 15, 2015

s/ Joshua S. Bratspies
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